SECTION 6
510(k) SUMMARY (CONT.)

510(k) Notification K 091666

GENERAL INFORMATION

Applicant:
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USA
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JUL 15 2009

Contact Person:
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Regulatory Consultant for OptiMedica Corporation
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USA
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Date Prepared: June 5, 2009

Classification:
21 CFR§878.4810, Class II
21 CFR§886.4390, Class II

Product Code:
GEX, HQF

Trade Name:
PASCAL® Photocoagulator

Generic/Common Name:
Laser instrument, surgical, powered
Laser, ophthalmic

Predicate Device
PASCAL Photocoagulator (K043486)

SECTION 6
510(k) SUMMARY (CONT.)

Intended Use
Intended for use in the treatment of ocular pathology in both the posterior and anterior segments.

Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

- proliferative and nonproliferative diabetic retinopathy
- macular edema
- choroidal neovascularization
- branch and central retinal vein occlusion
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments
- iridotomy, iridectomy and trabeculoplasty in angle closure and open angle glaucoma.

Product Description
The PASCAL Photocoagulator is an integrated system comprising of solid state aiming and treatment lasers, control electronics, graphical user interface, slit-lamp and table. It is intended for use in the treatment of ocular pathology in both the posterior and anterior segments.

The proposed PASCAL Photocoagulator includes design modifications to the performance specifications, available scan patterns, outer housing and software to enhance product performance. No changes to the laser or the product safety have been made. The PASCAL Photocoagulator maintains the same indication for use as the predicate device, the PASCAL Photocoagulator (K043486).

Substantial Equivalence
The PASCAL Photocoagulator is substantially equivalent to the predicate device with regard to function, intended use and physical characteristics. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the proposed PASCAL Photocoagulator is substantially equivalent to the predicate device.

Testing in Support of Substantial Equivalence Determination
All necessary bench testing was conducted on the proposed PASCAL Photocoagulator to support a determination of substantial equivalence to the predicate device.

Summary
The PASCAL Photocoagulator is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2009

Optimedica Corporation
c/o Experien Group LLC.
Darlene Crockett-Billig
155-A Moffit Park Drive, Suite 210
Sunnyvale, CA 94089

Re: K091666
Trade/Device Name: PASCAL Photocoagulator
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 30, 2009
Received: July 1, 2009

Dear Ms. Crockett-Billig

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091666

Device Name: PASCAL® Photocoagulator

Intended for use in the treatment of ocular pathology in both the posterior and anterior segments.

Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

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- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments
- iridotomy, iridectomy and trabeculoplasty in angle closure and open angle glaucoma.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091666